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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,833	02/12/2002	Dominique Bourel	065691-0260	8788

22428 7590 11/02/2004

FOLEY AND LARDNER
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3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,833

Applicant(s)

BOUREL ET AL.

Examiner

David A Saunders, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 30-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Amendment of 8/5/04 has been entered. Claims 30-43 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment has overcome previously stated rejections under 35 USC 112 and 102.

Claims 30-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 30, the preamble recites "Ig fraction"; steps c) – e) refer to various "fraction(s)"; however, it is not clear which is the "Ig fraction".

In claim 30 part d) "the hapten DNP" lacks antecedent basis, since no preceeding step recites "hapten." Likewise note claim 35, last line.

In claim 30, part a) "lysin" should be spelled as --lysine--.

Claims 33 and 35-38 are each indefinite as method claims, since they do not positively recite method steps; note that claim 30 is a product by process claim; thus it is not clear that the steps recited in claim 30 constitute the "method" of claims 33-38.

Other informalities in claims 31-38 are:

In claim 31 "the selected fraction" is singular, while in claim 30, step e), applicant recites "fractions" in the plural; consistency is required.

In claim 33 "the Ig fractions" is recited in the plural, while in claim 30, in the preamble, applicant recites "Ig fraction" in the singular; consistency is required. It is

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also unclear what applicant intends by reciting "prepared from polyvalent Igs." Since "polyvalent Igs" are adsorbed in step a) of claim 30, what feature of claim 30 does dependent claim 33 further limit?

In claim 37, "the Igs retained in step b)" lack antecedent basis, since step b) recites nothing about retaining.

In claim 38 "the adsorption step" lacks antecedent basis, since claim 30 recites "adsorbing" rather than "adsorption".

Claim 42 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of "neurological conditions" selected from those recited in dependent claim 43, does not reasonably provide enablement for the treatment of any and all "neurological conditions". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicant's disclosure has taught that the Ig fraction is capable of modulating processes that result from an immunological and/or inflammatory condition (e.g. page 2, lines 14+).

The genus of "neurological conditions" includes numerous diseases, syndromes, and conditions which do not result from an immunological or inflammatory response. For example, impaired or excessive expression of receptors, reduced or excess synthesis of neurotransmitters, excess accumulation of lipids, apoptosis of neural cells, malignant transformation of neural cells, etc can occur independently of any immunological or inflammatory response. One of skill would not expect such "neurological conditions" to be treatable with the disclosed Ig fraction.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd

October 25, 2004

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182
1044